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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,270	01/04/2002	Ping Zhou	784CIP2BDV1	6432

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EXAMINER	
RAO, MANJUNATH N	
ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 01/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/037,270	ZHOU ET AL.	
	Examiner	Art Unit	
	Manjunath N. Rao, Ph.D.	1652	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *10,11 and 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10,11 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 10, 11 and 20 are currently pending in this application.

Election/Restrictions

Examiner regrets the inadvertent mailing of the Restriction requirement even though applicants had filed an amendment claiming a single amino acid sequence as the subject of their invention. Any inconvenience caused in this regard is regretted.

Claim Objections

Claim 10 is objected to because of the following informalities: Claim 10 is drawn to an isolated polypeptide encoded by a nucleotide acid sequence. However, applicants do not provide the SEQ ID NO for the claimed polypeptide. Without a SEQ ID NO for the polypeptide it would not be possible for the Examiner to do an accurate search. Examiner urges applicants to provide a SEQ ID NO for the claimed polypeptide. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10, 11 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 10 is drawn to a polypeptide encoded by the polynucleotide with SEQ ID NO:482. However, applicants do not provide the actual activity of

the encoded polypeptide in the claim or in the specification. Therefore, the metes and bounds of the claim is not clear to the Examiner. It is not clear to the Examiner as to applicants are claiming a polypeptide of any length and of any activity or no activity or a specific polypeptide of a specific amino acid length having a specific activity.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 10, 11 and 20 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The applicant has not asserted at least one utility for the claimed isolated polypeptide. The broadly claimed polypeptides and its fragments are based on the transcription and translation of the polynucleotide with SEQ ID NO:428. Other than providing the polynucleotide with SEQ ID NO:428, the specification provides little functional characterization of the encoded protein; that it has 37% sequence identity to a chicken trypsinogen. The specification simply lists general use of (see entire specification) polypeptides including uses to treat a long list of human disorders, however, there is no information that links the use of the polypeptide encoded by SEQ ID NO:428 and its fragments to any specific disease state. Thus it is not possible for the Examiner to associate any utility of the claimed polypeptides and its fragments to a substantial or specific utility. Further, while the specification discloses that claimed polypeptide and its fragments will be used to generate antibodies, or that it will be used as molecular weight markers or in research, such utilities are not a utility specific to the claimed polynucleotide sequence.

Claims 10, 11 and 20 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Applicant is referred to the revised interim guidelines concerning compliance with utility requirement of U.S.C. 101, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10, 11 and 20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 10, 11 and 20 are directed to polypeptide encoded by the polynucleotide with SEQ ID NO:428 or polypeptides encoded by polynucleotides that are 99% identical to SEQ ID NO:428. including variants and mutants. Claims 10 and 20 are rejected under this section of 35 USC 112 because the claims are directed to a genus of polypeptides including modified polypeptide sequences, modified by at least one of deletion, addition, insertion and substitution of an amino acid residue that have not been disclosed in the specification. No description has been provided of the polypeptide sequences encompassed by the claim. No information, beyond

the characterization of the encoding polynucleotide as SEQ ID NO:428 has been provided by applicants which would indicate that they had possession of the claimed genus of polypeptides. The specification does not contain any disclosure of the function of the polypeptide sequences encompassed by the claims, including fragments and variants within the scope of the claimed genus. The genus of polypeptides claimed is a large variable genus including peptides which can have a wide variety of functions and with the potentiality of generating many different antibodies. Therefore many functionally unrelated polypeptides are encompassed within the scope of these claims. The specification discloses only encoding polynucleotide which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10, 11 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Brodrick et al. (J. Biol. Chem., 1978, Vol. 253(8):2732-6). This rejection is based upon the public availability of a printed publication. Claims 10 and 20 of the instant application are drawn to an isolated polypeptide encoded by the polynucleotide with SEQ ID NO:428. The specification

indicates that the polypeptide has similarities to a trypsinogen. Therefore it would be reasonable for those skilled in the art to conclude that the encoded polypeptide has trypsinogen activity. Brodrick et al. disclose a polypeptide isolated from human source with trypsinogen activity. However, the reference does not disclose the amino acid sequence or the polynucleotide sequence encoding the polypeptide which are indeed considered as inherent characteristics of polypeptides. Therefore, based on the similar activity and the source of the reference and claimed polypeptide, Examiner takes the position that the reference polypeptide is indeed the polypeptide encoded by the polynucleotide with SEQ ID NO:428 or a polynucleotide that is at least 99% identical to SEQ ID NO:428. Thus Brodrick et al. anticipate claims 10, 11 and 20 as written.

Since the Office does not have the facilities for examining and comparing applicants' protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald* et al., 205 USPQ 594.

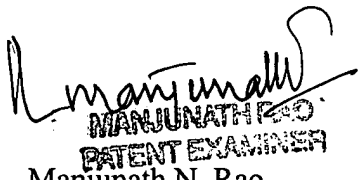
Conclusion

None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 703-306-5681. The examiner can normally be reached on 7.30 a.m. to 4.00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0196.



Manjunath N. Rao
January 5, 2004